	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	**Recommendation** **NB-MED/2.15/Rec1**

Title:	**Voluntary certification at an intermediate stage of manufacture**
Chapter:	**2.15 Other**

Text:	**MDD „results of any assessment and verification operation, which where appropriate have been carried out in accordance with this Directive at an intermediate stage of manufacture“** **IVD “During the conformity assessment procedure for a device, the manufacturer and, if involved, the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate state of manufacture.”**
Key words:	**certificate, certificate of competence, intermediate stage of manufacture, quality assurance, statement of competence, supplier, technical assessment**

1. Purpose

The purpose of this recommendation is to provide guidance on the minimum content of voluntary certificates relating to the quality assurance and technical assessment for an intermediate stage of manufacture; this includes processes that require validation and verification activities such as sterilisation, inactivation of viruses and transmissible agents, coating of implants etc. This is in the interests of avoiding duplication of inspection or certification and will enable the results of quality assurance system assessment of a supplier providing a product/service at an intermediate stage of manufacture to be taken into account by the Notified Body auditing the manufacturer of the medical devices (see table 1).

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD	article: 11.7	
IVDD	article: 9.5	

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2. Recommendation

- Separately from the quality assurance system assessment but to be taken into account for delivering the regulatory certification where appropriate, a „certificate of competence“ indicating compliance with specific requirements of the medical devices manufacturer may be given at an intermediate stage of manufacture. Any such certificate should be taken into account by the Notified Body undertaking conformity assessment of the medical device manufacturer, having due regard to its overall responsibilities.

- The relevance of the types of certificate referred to above is recognised in Directive 93/42/EEC, Article 11, paragraph 7 and in the IVD-Directive, Article 9, paragraph 5.

  Note: Similar certificates may be appropriate and helpful in avoiding duplication of assessment in the context of the Directive 90/385/EEC.

- The use of these certificates should be restricted to instances where the intermediate stage of manufacture represents a stage in the overall production of the device which is distinct and demanding of audit (see recommendation NB-MED/2.5.2/Rec1 *Subcontracting - QS related*.

- Examples of certificates are included in table 2.

Table 1: Information about the minimum content of voluntary certificates

Content \ Type of certificate	A [1]	B [2]	C [3]
Number of certificate [4]	+	+	
Date of issue	+	+	
Date of the end of validity [5]	+	+	
Title [6]	+	+	
Main text:			
- reference to national regulations	o	o	
- text [7]	+	+	
Supplier:			
- Name	+	+	
- Address	+	+	
Representatives [8]:			
- Name	o	o	
- Address	o	o	
Product/service concerned:			
a) - Name of product/service	+	+	
- Nomenclature code	o	o	
b) - Name/Identification of the model/type	o	o	
c) - Series or batch number	o	o	
Scope of quality system [9]	+	-	
Specific conditions of validity if any	o	o	
Certification organisation:			
- Notified Body Number (where applicable)	+	+	
- Authorised signature	+	+	
- Statement of competence [10] (if applicable)	+	+	
- Name and address	o	o	
- Tel./Fax-No.	o	o	
Identification of change [11]:	o	o	
- issued			
- modified			
- refused			
- withdrawn			
- extended			
- renewal			

explanation of footnotes see next page

+ required
o optional (if issued)
- not required

Note: The matter of **interlinking of certificates** has been considered and is recognised to be an administrative responsibility of the NB and should be traceable through the file of the NB. Inclusion of an cross-reference on the certificates themselves, however, would lead to practical difficulties.

Explanation of footnotes:

1 QUALITY SYSTEM FOR AN INTERMEDIATE STAGE OF MANUFACTURE

2 TECHNICAL ASSESSMENT FOR AN INTERMEDIATE STAGE OF MANUFACTURE

3 Further examples not yet proposed

4 unique within the particular certification organisation

5 see: Date of issue; end is limited. Proposal for text*: „This certificate is valid for x years from the date of issue".* For annex II and III maximum validity 5 years (comment/recommendation: required and desirable for all certificates)

6 necessary for identification of the type of certificate (i.e. conformity assessment procedure under which issued in the case of certificates covered by the Directive or purpose of certificates where supported by the Directives)

7 text samples relating to the different certificates see on table 2 (text is not prescribed)

8 if applicable; could be e.g. authorised representative, responsible representative

9 Scope of quality system in terms of , for example, facilities or activities covered

10 If appropriate, the certificate should include the statement „the assessment and verification operations performed in the course of this certification where conducted using demonstrated expertise in relation to Notified Body conformity assessment under directive ... [specify]."

11 In case of change of the design the use of an **addendum** is an option, but not mandatory. Where issued, the addendum should (a) include the note: *„This addendum is only valid if attached to the certificate mentioned above."* and (b) make clear the change to which it relates.

Table 2: Examples of text for voluntary certificates issued for an intermediate stage of manufacture

Type of certificate	**examples** for: **Title** / **Main text**
A	***Quality system certificate* for an intermediate stage of manufacture** We hereby certify that the quality assurance system of the supplier mentioned below is in accordance with the requirements of EN 46001/EN 46002[1] relating to medical devices for production and final control without the supplier being a manufacturer in the sense of Article 1 (f) of the Directive 93/42/EEC on medical devices [or the IVD-Directive]. [1] Delete as appropriate (EN 46001 or EN 46002 may be chosen by the person responsible for the intermediate stage of manufacturing according to whether or not the technical file on the product is to be submitted to the manufacturer of the medical device).
B	***Technical assessment certificate* for an intermediate stage of manufacture** We hereby certify that the technical files, as appropriate at this intermediate stage of manufacture, for the specific _____ (product/product range/product family) detailed on the attached schedule support the subsequent conformity assessment of the relevant medical devices with the applicable Essential Requirements of EC Directive ... [specify].
C	*not yet proposed*

NB-MED	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Rationale and history sheet to NB-MED/2.15/Rec1**

Title:	**Voluntary certification at an intermediate stage of manufacture**

Rev. 1: In general the origin of this NB-MED Recommendation comes from the draft NB-MED recommendation „Contents of certificates“ (document NBM/95/98). Since the NB-MED meeting on June 9 & 10, 1998 two recommendations were developed in parallel:

- NB-MED/2.5.1/Rec4 „Content of mandatory certificates“
- NB-MED/2.15/Rec1 „Certification at an intermediate stage of manufacture.

Therefor it is linked to the rationale & history sheet of the NB-MED/2.5.1/Rec4 „Content of mandatory certificates“.

Notified Body Meeting, Brussels, April 29 & 30, 1996:
EUROMCONTACT presented a proposal for a certificate of compliance with specific requirements of a contact lens manufacturer and evidence of conformity with the EN 46000 series in the case of a supplier of contact lens blanks. While not mandatory under Directive 93/42/EEC the proposal was accepted subject to modification to ensure purpose of the contact lens blanks, is included in the certificate.

Notified Body Meeting, Brussels, February 4 & 5, 1997:
The "certification" of subcontractors (sterilisation) was discussed. The question was also addressed in the document NBM/13/97. The MDD, Article 11, paragraph 7 provided the possibility for having to take account of qualification measures in an intermediate stage of production in the conformity assessment procedure. One possibility for qualification was certification to ISO 9001/2 or 46001/2. After a successful certification, a "certificate of competence" could be issued. Mr **Mestmacher**/RWTÜV agreed to send the Commission the certificate he used. The Commission declared its willingness to develop a uniform sample (see also item 8.2).

Notified Body Meeting, Brussels, June 9 & 10, 1998:
NB-MED discussed the draft NB-MED recommendation NB-MED/2.5.1/Rec4 „Content of certificates“ (document NBM/95/98) especially the principle of the minimum content and the both kinds of certificates (required/only supported by the directives). Mr. Lally/BSI reported about a meeting within the UK Notified Bodies and it was the common position to reject this particular document in its current from. Some aspects are too prescribed and on the other hand the table 3 relating to voluntary certificates delivered at an intermediate stage of manufacture is not supported at all, because it is not an absolute part of the remit of the Notified Bodies to undertake certification of work outside the directive. They may do it but not by influence as part of the role as a Notified Body. This opinion covers also the opinion of the MDA. Mr. Lally, Mr. Jepson/SGS. and

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Mr. Ruys/KEMA promised to send their comments directly to the NBRG. NBRG was asked to finalise the draft recommendation on their meeting on 11./12.06.98.
Confirmed to be at Stage: 1

Meeting of NBR Group, Brussels, June 11 & 12, 1998:
NBRG discussed the results of the NB-MED plenary meeting on 09./10.06.98. Mr. Ruys, Mr. Lally and Mr. Jepson submitted written comments and suggestions to the effect that:

- the sample of a certificate at an intermediate stage of manufacturing should be separated from this recommendation as it is voluntary form of certification and not mandatory under the Directives.
- various editorial suggestions for improvement of the contents of the mandatory certificate.

NBRG considered these comments and suggestions, adopted the main points of principle and introduced **two separate NB-MED recommendations**:

- NB-MED/2.5.1/Rec4 „Content of mandatory certificates“
- NB-MED/2.15/Rec1 „Certification at an intermediate stage of manufacture“.

NBRG noted that while the MDD, Article 11 (7) [and IVD-Directive, Article 9 (5)] makes reference to such certification, this is not the case for the AIMD but manufacturers regulated by this Directive see a clear requirement for such certification in their case.
NBRG agreed to send **both** revised documents, with the belonging "Rationale and history" sheets to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1998.
Revision no: 1 (NB-MED/2.15/Rec1 „Certification at an intermediate stage of manufacture“)
(Revision no: 2 (NB-MED/2.5.1/Rec4 „Content of mandatory certificates“))
Confirmed to be at Stage: 2

Rev. 2: Meeting of NBR Group, Lübeck, August 31 & September 1, 1998:
NBRG made some editorial changes and clarification concerning the reason of this document (e.g.: it was agreed to use the wording „voluntary“ instead „optional“).
NBRG agreed to send the revised document, with the belonging "Rationale and history" sheets to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1998.
Revision no: 2
Confirmed to be at Stage: 2

Notified Body Meeting, Brussels, November 3 & 4, 1998:
NB-MED accepted the tabled document without changes. But the members of NB-MED made a general discussion of the wording "where applicable" in the context of "Notified Body Number" (page 3, table 1, penultimate line). The document was confirmed now to be at stage 3, the rationale and history sheet will be changed subsequently. It will be incorporated in the booklet of NB-MED recommendations and will be also presented to the Medical Devices Experts Group.
Confirmed to be at Stage: 3

Rev. 3: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to rework the NB-MED Recommendations in light of the IVD-directive.

Meeting of NBR Group, Cologne, February 3, 2000:
The work results of a small task force (task: reworking the Recommendations) were presented to that NBRG-meeting.
The tabled revised Recommendation was discussed and NBRG agreed that the document, as discussed and revised, should be presented for adoption at the February/March NB-MED Plenary meeting. Only some editorial changes were made.
Revision no: 3
stage 2

Notified Body Meeting, Brussels, February 29, & March 1, 2000:
Dr. Holland reported that the current and valid/accepted stage 3 document (see NBM/123/99) was in the meanwhile revised by the NBRG/IVD task force (see NBM/41/00). Changes were made in light of the IVDD. Some verbal comments have arrived - especially made by the MDA - and there could be a need for incorporation those. The NB-MED agreed that further development on this Recommendation will be made within **NBRG**. A revised draft document should be presented at the next plenary (IVDD) meeting in June. Up to there the already accepted stage 3 document will be kept still valid.

Meeting of NBR Group, Brussels, April 10 &11, 2000:
NBRG stated that the Recommendation was revised in light of the IVD-Directive and confirmed as correct. It was also confirmed that this certificate is relevant to both the MDD and AIMD as recognised in MDD, Article 11, paragrapf 7 and in the IVDD, Article 9, paragraph 5. NBRG further agreed that the Recommendation as it now stands - and already presented to the plenary in March - should be presented to the plenary in June
Revision no: 3
stage 2

Notified Body Meeting, Brussels, June 6 & 7, 2000:
The document (NBM/60/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 3